

PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents
United States Patent and Trademark
Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 19 October 2000 (19.10.00)	Applicant's or agent's file reference PG3619/PCT
International application No. PCT/GB00/00919	Priority date (day/month/year) 10 March 1999 (10.03.99)
International filing date (day/month/year) 10 March 2000 (10.03.00)	
Applicant DAVIES, Michael, Birsha	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
25 September 2000 (25.09.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<p>The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland</p> <p>Facsimile No.: (41-22) 740.14.35</p>	<p>Authorized officer Olivia TEFY</p> <p>Telephone No.: (41-22) 338.83.38</p>
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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING
OF A CHANGE(PCT Rule 92bis.1 and
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

TEUTEN, Andrew, J.
GlaxoSmithKline
corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP
ROYAUME-UNI

Date of mailing (day/month/year)
04 juillet 2001 (04.07.01)

Applicant's or agent's file reference
PG3619/PCT

IMPORTANT NOTIFICATION

International application No.
PCT/GB00/00919

International filing date (day/month/year)
10 mars 2000 (10.03.00)

1. The following indications appeared on record concerning:

☒ the applicant ☐ the inventor ☒ the agent ☐ the common representative

Name and Address

TEUTEN, Andrew, J.
Glaxo Wellcome plc
Glaxo Wellcome House, Berkeley
Avenue
Greenford
Middlesex UB6 0NN
United Kingdom

State of Nationality

State of Residence

Telephone No.

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Facsimile No.

020 8966 8838

Teleprinter No.

2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:

☐ the person ☐ the name ☒ the address ☐ the nationality ☐ the residence

Name and Address

TEUTEN, Andrew, J.
GlaxoSmithKline
Corporate Intellectual Property
Two New Horizons Court
Brentford
Middlesex TW8 9EP
United Kingdom

State of Nationality

State of Residence

Telephone No.

020 8966 8412

Facsimile No.

020 8966 8838

Teleprinter No.

3. Further observations, if necessary:

4. A copy of this notification has been sent to:

☒ the receiving Office ☐ the designated Offices concerned
☐ the International Searching Authority ☒ the elected Offices concerned
☒ the International Preliminary Examining Authority ☐ other:

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer

Maria Victoria CORTIELLO

Telephone No.: (41-22) 338.83.38



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PG3619/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/00919	International filing date (day/month/year) 10/03/2000	Priority date (day/month/year) 10/03/1999
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet. <input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT). These annexes consist of a total of 4 sheets.
3. This report contains indications relating to the following items: I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input checked="" type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application

Date of submission of the demand 25/09/2000	Date of completion of this report 19.06.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Lager, J Telephone No. +49 89 2399 2957 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00919

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-12 as originally filed

Claims, No.:

1-30 as received on 24/03/2001 with letter of 19/03/2001

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 31-33

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00919

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 30.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 30.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims 1-29

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00919

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-29
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-29
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/00919

Section III.

1. Claim 30 has not been searched, cf. Rule 66(1)(e) PCT.

Section V.

1. The closest prior art is represented by document US-A-5 568 807 (=D1) which discloses a device according to the preambles of independent of claims 1 and 13.
 - 1.1 The concept of covering means which is in biased contact with the dose and which performs the function of a one-way valve is not disclosed in any of the available prior art documents.
Independent claims 1 and 13 do therefore fulfil the requirements of Article 33(2)-(3) PCT, see also Section VIII below.
2. Dependent claims 2-12 and 14-29 define preferred embodiments of the dose protector of claims 1 or 13.
3. Claims 1-29 do therefore fulfil the requirements of Article 33(2)-(4) PCT.

Section VII.

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Section VIII.

1. Although claims 1 and 13 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter, i.e. overlapping scope, and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/00919

that subject-matter.

The aforementioned claims therefore **lack conciseness**.

Hence, claims 1 and 13 do not meet the requirements of Article 6 PCT.

- 1.1 In order to overcome this objection, it would have been appropriate to draft the relevant subject-matter in terms of a single independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).
2. Moreover, claims 1-7 and 13-15 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined.
The claims attempt to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem.
The **essential technical features** necessary for enabling the skilled man in the art to achieve these results should be added, see PCT Guidelines chapter III-4.4.
3. The vague and imprecise statement in the description on page 12, last paragraph, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

CLAIMS

- 5 1. A dose protector for use in an inhaler comprising a housing defining an airway; a dose of medicament optionally retained in a dose container; and covering means characterised in that said means is in biased contact with said dose or container retaining the dose and only opens in response to airflow through and/or pressure drop across the airway in a first direction but not in a second, opposite direction.
- 10 2. A dose protector as claimed in claim 1 wherein the covering means is only open in the presence of airflow through and/or pressure drop across the airway in a first direction after which it returns to its resting position.
- 15 3. A dose protector as claimed in claim 1 or claim 2 wherein the airflow through and/or pressure drop across the airway is caused by patient inhalation.
- 20 4. A dose protector as claimed in claims 1 to 3 wherein the said covering means senses airflow through and/or pressure across drop the airway and responds thereto.
5. A dose protector as claimed in claim 4 incorporating electronic means for sensing airflow through and/or pressure drop across the airway and/or means of responding thereto.
- 25 6. A dose protector as claimed in any preceding claim wherein the covering means responds by covering the dose more effectively when the airflow through and/or pressure drop across the airway is in a second direction.

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7. A dose protector as claimed in claim 6 wherein airflow through and/or pressure drop across the airway in a second direction is caused by the patient exhaling.
- 5 8. A dose protector as claimed in claims 1 to 7 where the covering means comprises one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.
- 10 9. A dose protector as claimed in any one of claims 1 to 8 wherein the dose is metered by volume of medicament or surface area.
- 10.A dose protector as claimed in claim 9 wherein the dose is metered by volume into a container.
- 15 11.A dose protector as claimed in claim 10 wherein the said container is a pocket.
- 12.A dose protector as claimed in any preceding claim wherein the dose or container retaining the dose has a surrounding rim.
- 20 13.A dose protector for use in an inhaler comprising a housing defining an airway; a pocket suitable for containing a dose of medicament; and characterised in that it comprises at least one sealing flap in biased contact with said pocket and providing a cover for the pocket; wherein the contact
- 25 between the at least one sealing flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction.
- 14.A dose protector as claimed in claim 13 wherein the sealing flap is spaced away from the pocket by the airflow once contact with the pocket is broken.

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5 15.A dose protector as claimed in claim 13 or claim 14 additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the at least one sealing flap and the pocket being broken by airflow through the airway in any direction.

16.A dose protector as claimed in claim 15 wherein the pocket has a surrounding rim.

10 17.A dose protector as claimed in any one of claims 13 to 16 wherein the said sealing flap vibrates in the airflow once the contact with the pocket is broken.

18.A dose protector as claimed in any one of claims 13 to 17 wherein the sealing flap is made of thermoset rubber.

15

19.A dose protector as claimed in any one of claims 13 to 18 wherein the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket.

20

20.A dose protector as claimed in claim 19 wherein the distance between the inside walls of the housing increases as the distance away from the pocket increases.

25

21.A dose protector as claimed in claims 1 to 12 wherein the said covering means is spaced away from the dose or container retaining a dose to coincide with the airflow through and/or pressure drop across in the first direction once the contact with the dose or container retaining the dose is broken.

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22. A dose protector as claimed in any one of claims 1 to 21 wherein the covering means vibrates in the airflow through and/or pressure drop across the airway in the first direction.

5 23. A dose container as claimed in claims 1 to 22 wherein the housing contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap.

10 24. A dose protector as claimed in any preceding claim wherein the said covering means protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination and loss of the dose or a combination thereof.

15 25. A dose protector as claimed in any preceding claim additionally comprising a fixed seal.

26. A dose protector as claimed in any one of claims 1 to 25, in combination with a dose of medicament.

20 27. An inhaler comprising a body, a mouthpiece, and a dose protector as claimed in any preceding claim.

25 28. An inhaler as claimed in claim 27 wherein the said inhaler is a dry powder inhaler.

29. An inhaler as claimed in claim 26 or claim 27 in combination with at least one dose of a medicament.

30 30. Use of an inhaler as claimed in any one of claims 27 to 29 for the administration of medicament.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference PG3619/PCT	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/ 00919	International filing date (day/month/year) 10/03/2000	(Earliest) Priority Date (day/month/year) 10/03/1999
Applicant GLAXO GROUP LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 6 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☒ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☒ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

1a

☐ None of the figures.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 00/00919

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 33
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☒ Claims Nos.: 27, 32
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Claims 27 and 32 contain references to the drawings contrary to the requirements of Rule 6.2(a) PCT.
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 00/ 00919

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

Line 1 after "housing" insert "(40)"
Line 2 after "container" insert "(20,30)"
Line 3 after "means" insert "(10)", after "means" insert "(10)"

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 27,32

Claims 27 and 32 contain references to the drawings contrary to the requirements of Rule 6.2(a) PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/00919

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 568 807 A (MECIKALSKI MARK B) 29 October 1996 (1996-10-29) abstract column 1, line 64 -column 2, line 4 column 4, line 28-67 figure 3	1-3,5, 7-13,25, 26,28-31
Y		6
A		4,14-24
X	US 5 447 151 A (BRUNET MICHEL ET AL) 5 September 1995 (1995-09-05) column 14, line 9-31	1-3,5, 7-13 4,6, 14-26, 28-31
A		

	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"Z" document member of the same patent family

Date of the actual completion of the international search

18 July 2000

Date of mailing of the international search report

01.08.00

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

Lager, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/00919

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 349 945 A (LAW BRIAN R ET AL) 27 September 1994 (1994-09-27) column 6, line 31-59; figures 6,7	1-3,5, 7-11,13 4,6,12, 14-26, 28-31
Y	--- WO 96 13161 A (ARADIGM CORP) 9 May 1996 (1996-05-09) page 14, line 22-28 page 29, line 25 -page 32, line 22	6
A	page 41, line 4-10	1-5, 7-26, 28-31
A	--- US 5 533 505 A (KAELLSTRAND GOERAN ET AL) 9 July 1996 (1996-07-09) abstract; figures	1-26, 28-31
A	--- US 4 664 107 A (WASS ANTHONY C L) 12 May 1987 (1987-05-12) abstract; figures	1-26, 28-31
A	--- US 5 823 183 A (LEITH FRANK A ET AL) 20 October 1998 (1998-10-20) abstract; figures 2A-2C -----	1-26, 28-31

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/00919

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5568807 A	29-10-1996	US 5483954 A AU 3003295 A EP 0769974 A WO 9534337 A US 5575281 A	16-01-1996 05-01-1996 02-05-1997 21-12-1995 19-11-1996
US 5447151 A	05-09-1995	FR 2667509 A WO 9205823 A WO 9205824 A FR 2667790 A	10-04-1992 16-04-1992 16-04-1992 17-04-1992
US 5349945 A	27-09-1994	AU 9060491 A DE 69108929 D DE 69108929 T EP 0559757 A WO 9209324 A	25-06-1992 18-05-1995 23-11-1995 15-09-1993 11-06-1992
WO 9613161 A	09-05-1996	US 5672581 A AU 685694 B AU 4194996 A CA 2203129 A EP 0785713 A JP 10509606 T US 5970973 A US 5873358 A US 6024090 A US 5941240 A US 5915378 A US 5743250 A US 5888477 A US 5884620 A	30-09-1997 22-01-1998 23-05-1996 09-05-1996 30-07-1997 22-09-1998 26-10-1999 23-02-1999 15-02-2000 24-08-1999 29-06-1999 28-04-1998 30-03-1999 23-03-1999
US 5533505 A	09-07-1996	EP 0558879 A AT 167067 T AU 666171 B AU 3499793 A BR 9306023 A CA 2131157 A CN 1080875 A,B CZ 9402084 A DE 69319100 D DE 69319100 T WO 9317728 A EP 0629136 A ES 2118223 T FI 944034 A GR 3027773 T HU 69090 A,B JP 7508184 T NO 943211 A NZ 249128 A RU 2105573 C SG 49134 A SK 104994 A ZA 9301520 A	08-09-1993 15-06-1998 01-02-1996 05-10-1993 18-11-1997 16-09-1993 19-01-1994 18-01-1995 16-07-1998 28-01-1999 16-09-1993 21-12-1994 16-09-1998 02-09-1994 30-11-1998 28-08-1995 14-09-1995 30-08-1994 26-01-1996 27-02-1998 18-05-1998 12-04-1995 06-09-1993
US 4664107 A	12-05-1987	AU 578915 B AU 3558384 A	10-11-1988 22-05-1985

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/00919

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4664107 A		CA 1236359 A	10-05-1988
		DE 3470844 D	09-06-1988
		EP 0147028 A	03-07-1985
		FI 852490 A,B,	24-06-1985
		JP 5048138 B	20-07-1993
		JP 61500254 T	20-02-1986
		WO 8501880 A	09-05-1985

US 5823183 A	20-10-1998	US 5692496 A	02-12-1997
		WO 9906092 A	11-02-1999
		EP 1003583 A	31-05-2000
		US 5988163 A	23-11-1999
		AU 3822097 A	22-02-1999

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/00919

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 568 807 A (MECIKALSKI MARK B) 29 October 1996 (1996-10-29) abstract column 1, line 64 -column 2, line 4 column 4, line 28-67 figure 3	1-3,5, 7-13,25, 26,28-31
Y		
A		6 4,14-24
X	US 5 447 151 A (BRUNET MICHEL ET AL) 5 September 1995 (1995-09-05) column 14, line 9-31	1-3,5, 7-13 4,6, 14-26, 28-31
A		
	--- -/--	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

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- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

18 July 2000

Date of mailing of the international search report

01.08.00

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Lager, J

INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 00/00919

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	US 5 349 945 A (LAW BRIAN R ET AL) 27 September 1994 (1994-09-27) column 6, line 31-59; figures 6,7	1-3,5, 7-11,13 4,6,12, 14-26, 28-31
Y	--- WO 96 13161 A (ARADIGM CORP) 9 May 1996 (1996-05-09) page 14, line 22-28 page 29, line 25 -page 32, line 22	6
A	page 41, line 4-10	1-5, 7-26, 28-31
A	--- US 5 533 505 A (KAELLSTRAND GOERAN ET AL) 9 July 1996 (1996-07-09) abstract; figures	1-26, 28-31
A	--- US 4 664 107 A (WASS ANTHONY C L) 12 May 1987 (1987-05-12) abstract; figures	1-26, 28-31
A	--- US 5 823 183 A (LEITH FRANK A ET AL) 20 October 1998 (1998-10-20) abstract; figures 2A-2C -----	1-26, 28-31

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB 00/00919

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 33
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by therapy
2. ☒ Claims Nos.: 27, 32
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
Claims 27 and 32 contain references to the drawings contrary to the requirements of Rule 6.2(a) PCT.
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 27,32

Claims 27 and 32 contain references to the drawings contrary to the requirements of Rule 6.2(a) PCT.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/00919

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5568807 A	29-10-1996	US 5483954 A	16-01-1996
		AU 3003295 A	05-01-1996
		EP 0769974 A	02-05-1997
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/00919

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 4664107 A		CA 1236359 A	10-05-1988
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PCT

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International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁷ : A61M 15/00	A1	(11) International Publication Number: WO 00/53248 (43) International Publication Date: 14 September 2000 (14.09.00)
<p>(21) International Application Number: PCT/GB00/00919</p> <p>(22) International Filing Date: 10 March 2000 (10.03.00)</p> <p>(30) Priority Data: 9905538.6 10 March 1999 (10.03.99) GB</p> <p>(71) Applicant (for all designated States except US): GLAXO GROUP LIMITED [GB/GB]; Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).</p> <p>(72) Inventor; and (75) Inventor/Applicant (for US only): DAVIES, Michael, Birsha [GB/GB]; Glaxo Wellcome plc, Park Road, Ware, Hertfordshire SG12 0DP (GB).</p> <p>(74) Agent: TEUTEN, Andrew, J.; Glaxo Wellcome plc, Glaxo Wellcome House, Berkeley Avenue, Greenford, Middlesex UB6 0NN (GB).</p>		<p>(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p>Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: IMPROVEMENTS RELATING TO AN INHALATION DEVICE</p> <p>(57) Abstract</p> <p>A dose protector for use in an inhaler comprising a housing (40) defining an airway; a dose of medicament optionally retained in a dose container (20, 30); and covering means (10) for said dose wherein covering means (10) for the dose only opens in response to airflow through and/or pressure drop across the airway in a first direction but not in a second, opposite direction.</p> <div data-bbox="868 1081 1331 1459"> </div>		

PCT

REQUEST

The undersigned requests that the present
International application be processed
according to the Patent Cooperation Treaty

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) PG3619/PCT

Box No. I TITLE OF INVENTION

Improvements relating to an inhalation device

Box No. II APPLICANT

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below).

Glaxo Group Limited
Glaxo Wellcome House
Berkeley Avenue
Greenford, Middlesex
UB6 0NN, GB

☐ This person is also inventor.

Telephone No. 020 8966 8000

Facsimile No. 020 8966 8838

Teleprinter No. 25456

State (i.e. country) of nationality:

GB

State (i.e. country) of residence:

GB

This person is applicant
for the purposes of:

☐

all designated
States

☒

all designated States except
the United States of America

☐

the United States
of America only

☐

the States indicated in the
Supplemental Box

Box No. III FURTHER APPLICANTS AND/OR (FURTHER) INVENTORS

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)

DAVIES, Michael Birsha
Glaxo Wellcome plc
Park Road
Ware
Hertfordshire, SG12 0DP
GB

This person is:

☐

applicant only

☒

applicant and inventor

☐

inventor only (If this check-box
is marked, do not fill in below.)

State (i.e. country) of nationality:

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State (i.e. country) of residence:

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This person is applicant
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the States indicated in
the Supplemental Box

☐ Further applicants and/or (further) inventors are indicated on a continuation sheet.

Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE

The person identified below is hereby/has been appointed to act on behalf
of the applicant(s) before the competent International Authorities as:

☒

agent

☐

common representative

Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country).

TEUTEN, Andrew J.
Glaxo Wellcome plc
Glaxo Wellcome House, Berkeley Avenue
Greenford, Middlesex
UB6 0NN
GB

Telephone No.: 020 8966 8000

Facsimile No.: 020 8966-8838

Teleprinter No.: 25456

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no agent or common representative is/has been appointed and the space above is used instead to
which correspondence should be sent.

Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):


Regional Patent

- ☒ **AP** **ARIPO Patent:** GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ **EA** **Eurasian Patent:** AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ **EP** **European Patent:** AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ **OA** **OAPI Patent:** BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line).....

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| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TM Turkmenistan..... |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TR Turkey..... |
| <input checked="" type="checkbox"/> HU Hungary..... | <input checked="" type="checkbox"/> TT Trinidad and Tobago..... |
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| <input checked="" type="checkbox"/> IL Israel..... | <input checked="" type="checkbox"/> UG Uganda..... |
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Box No. VI PRIORITY CLAIM		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box		
		Where earlier application is		
Filing Date of Earlier Application (day/month/year)	Number Of earlier application	national application: country	regional application:* regional Office	International application: Receiving Office
item (1) (10.03. 99) 10 March 1999	9905538.6	GB		
item (2)				
item (3)				
<input type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): _____ * Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that early application was filed (Rue 4.10(b)(ii)). See Supplemental Box.				
Box No. VII INTERNATIONAL SEARCHING AUTHORITY				
Choice of International Searching Authority (ISA) <i>two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used:</i> ISA/		Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority): Date (day/month/year) Number Country (or regional office)		
Box. VIII CHECK LIST; LANGUAGE OF FILING				
This international application contains the following number of sheets: request : 3 description (excluding sequence listing part) : 12 claims : 5 abstract : 1 drawings : 4 sequence listing part of description : _____ Total number of sheets : 25		This international application is accompanied by the item(s) marked below: 1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input type="checkbox"/> other (specify):		
Figure of the drawings which should accompany the abstract:		Language of filing of the International application: English		
Box No. IX SIGNATURE OF APPLICANT OR AGENT				
Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).				
				
Andrew J. TEUTEN Agent for the Applicants				

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1. Date of actual receipt of the purported international application _____	2. Drawings
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PCT

FEE CALCULATION SHEET

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Annex to the Request

International application No.

Date stamp of the receiving Office

Applicant's or agent's
file reference

PG3619/PCT

Applicant

Glaxo Group Limited et al

CALCULATION OF PRESCRIBED FEES

1. TRANSMITTAL FEE

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2. SEARCH FEE

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International Search to be carried out by

(If two or more International Searching Authorities are competent in relation to the international application, indicate the name of the Authority which is chosen to carry out the international search.)

3. INTERNATIONAL FEE

Basic Fee

The international application 25 sheets.

first 30 sheets

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Designation Fees

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£560.00

D

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4. FEE FOR PRIORITY DOCUMENT

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5. TOTAL FEES PAYABLE

£1517.00

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MODE OF PAYMENT

☒ authorization to charge
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D01030

9 March, 2000

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Date (day/month/year)

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BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
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CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
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CLAIMS

1. A dose protector for use in an inhaler comprising a housing defining an airway; a dose of medicament optionally retained in a dose container; and
5 covering means for said dose wherein covering means for the dose only opens in response to airflow through and/or pressure drop across the airway in a first direction but not in a second, opposite direction.
2. A dose protector as claimed in claim 1 wherein the covering means is only
10 open in the presence of airflow through and/or pressure drop across the airway in a first direction after which it returns to its resting position.
3. A dose protector as claimed in claim 1 or claim 2 wherein the airflow
15 through and/or pressure drop across the airway is caused by patient inhalation.
4. A dose protector as claimed in any one of claims 1 to 3 wherein the
20 covering means is in biased contact with the dose or container retaining the dose.
5. A dose protector as claimed in claims 1 to 3 wherein the said covering
means senses airflow through and/or pressure across drop the airway and responds thereto.
- 25 6. A dose protector as claimed in claim 5 incorporating electronic means for sensing airflow through and/or pressure drop across the airway and/or means of responding thereto

7. A dose protector as claimed in any preceding claim wherein the covering means responds by covering the dose more effectively when the airflow through and/or pressure drop across the airway is in a second direction
- 5 8. A dose protector as claimed in claim 7 wherein airflow through and/or pressure drop across the airway in a second direction is caused by the patient exhaling.
- 10 9. A dose protector as claimed in claims 1 to 8 where the covering means comprises one or more poppet valves, diaphragm valves, rotary valves, reciprocating valves, sealing flaps or a combination thereof.
- 15 10. A dose protector as claimed in any one of claims 1 to 9 wherein the dose is metered by volume of medicament or surface area.
- 20 11. A dose protector as claimed in claim 10 wherein the dose is metered by volume into a container.
12. A dose protector as claimed in claim 11 wherein the said container is a pocket.
- 25 13. A dose protector as claimed in any preceding claim wherein the dose or container retaining the dose has a surrounding rim.
14. A dose protector for use in an inhaler comprising a housing defining an airway; a pocket suitable for containing a dose of medicament; and at least one sealing flap in biased contact with said pocket and providing a cover for the pocket; wherein the contact between the at least one sealing

flap and the pocket is broken by airflow through the airway in a first direction but not in a second opposite direction.

5 15. A dose protector as claimed in claim 14 wherein the sealing flap is spaced away from the pocket by the airflow once contact with the pocket is broken.

10 16. A dose protector as claimed in claim 14 or claim 15 additionally comprising a closure mechanism wherein the at least one sealing flap is held in contact with the pocket by a closure means which prevents the contact between the at least one sealing flap and the pocket being broken by airflow through the airway in any direction.

15 17. A dose protector as claimed in claim 16 wherein the pocket has a surrounding rim.

20 18. A dose protector as claimed in any one of claims 14 to 17 wherein the said sealing flap vibrates in the airflow once the contact with the pocket is broken.

19. A dose protector as claimed in any one of claims 14 to 18 wherein the sealing flap is made of thermoset rubber.

25 20. A dose protector as claimed in any one of claims 14 to 19 wherein the sealing flap is of equivalent or slightly reduced width relative to the distance between the inside walls of the housing at the base of the walls of the housing where the sealing flap is in contact with the pocket.

21. A dose protector as claimed in claim 20 wherein the distance between the inside walls of the housing increases as the distance away from the pocket increases.
- 5 22. A dose protector as claimed in claims 1 to 13 wherein the said covering means is spaced away from the dose or container retaining a dose to coincide with the airflow through and/or pressure drop across in the first direction once the contact with the dose or container retaining the dose is broken.
- 10 23. A dose protector as claimed in any one of claims 1 to 22 wherein the covering means vibrates in the airflow through and/or pressure drop across the airway in the first direction.
- 15 24. A dose container as claimed in claims 1 to 23 wherein the housing contains a valve flap such that when the airflow is in a second opposite direction, the airflow exits the housing by means of the valve flap.
- 20 25. A dose protector as claimed in any preceding claim wherein the said covering means protects the dose from the patient exhaling into the device, moisture contamination, particulate contamination and loss of the dose or a combination thereof.
- 25 26. A dose protector as claimed in any preceding claim additionally comprising a fixed seal.
27. A dose protector substantially as described in the accompanying Figures 1a to 9.

28. A dose protector as claimed in any one of claims 1 to 27, in combination with a dose of medicament.
- 5 29. An inhaler comprising a body, a mouthpiece, and a dose protector as claimed in any preceding claim.
30. An inhaler as claimed in claim 29 wherein the said inhaler is a dry powder inhaler.
- 10 31. An inhaler as claimed in claim 28 or claim 29 in combination with at least one dose of a medicament.
32. An inhaler substantially as described in the accompanying Figure 6 and 9.
- 15 33. Use of an inhaler as claimed in any one of claims 29 to 32 for the administration of medicament.

PCT

REC'D 21 JUN 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PG3619/PCT	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/GB00/00919	International filing date (day/month/year) 10/03/2000	Priority date (day/month/year) 10/03/1999
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

- ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

Date of submission of the demand 25/09/2000	Date of completion of this report 19.06.2001
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Lager, J Telephone No. +49 89 2399 2957 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00919

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-12 as originally filed

Claims, No.:

1-30 as received on 24/03/2001 with letter of 19/03/2001

Drawings, sheets:

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☒ the claims, Nos.: 31-33

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/00919

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 30.

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for the said claims Nos. 30.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Yes: Claims 1-29

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/00919

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-29
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-29
	No:	Claims	

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Section III.

1. Claim 30 has not been searched, cf. Rule 66(1)(e) PCT.

Section V.

1. The closest prior art is represented by document US-A-5 568 807 (=D1) which discloses a device according to the preambles of independent of claims 1 and 13.
 - 1.1 The concept of covering means which is in biased contact with the dose and which performs the function of a one-way valve is not disclosed in any of the available prior art documents.
Independent claims 1 and 13 do therefore fulfil the requirements of Article 33(2)-(3) PCT, see also Section VIII below.
2. Dependent claims 2-12 and 14-29 define preferred embodiments of the dose protector of claims 1 or 13.
3. Claims 1-29 do therefore fulfil the requirements of Article 33(2)-(4) PCT.

Section VII.

1. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
2. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Section VIII.

1. Although claims 1 and 13 have been drafted as separate independent claims, they appear to relate effectively to the same subject-matter, i.e. overlapping scope, and to differ from each other only with regard to the definition of the subject-matter for which protection is sought or in respect of the terminology used for the features of

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/00919

that subject-matter.

The aforementioned claims therefore **lack conciseness**.

Hence, claims 1 and 13 do not meet the requirements of Article 6 PCT.

- 1.1 In order to overcome this objection, it would have been appropriate to draft the relevant subject-matter in terms of a single independent claim followed by dependent claims covering features which are merely optional (Rule 6.4 PCT).
2. Moreover, claims 1-7 and 13-15 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined.
The claims attempt to define the subject-matter in terms of the result to be achieved which merely amounts to a statement of the underlying problem.
The **essential technical features** necessary for enabling the skilled man in the art to achieve these results should be added, see PCT Guidelines chapter III-4.4.
3. The vague and imprecise statement in the description on page 12, last paragraph, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

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